

**UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF TENNESSEE**

---

**UNITED STATES OF AMERICA  
[UNDER SEAL],**

**PLAINTIFF,**

**v.**

**[UNDER SEAL],**

**DEFENDANT.**

---

**CIVIL ACTION NO.**

**FILED UNDER SEAL  
PURSUANT TO  
31 U.S.C. § 3730(b)(2)**

**COMPLAINT**

**UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF TENNESSEE**

---

**UNITED STATES OF AMERICA  
*EX REL.***

**SAMUEL ADAM COX III,  
  
PLAINTIFF-RELATOR,**

**v.**

**SMITH & NEPHEW, INC.,  
  
DEFENDANT.**

---

**CIVIL ACTION NO.**

**FILED UNDER SEAL  
PURSUANT TO  
31 U.S.C. § 3730(b)(2)**

**JURY TRIAL DEMAND**

## **COMPLAINT**

1. This is an action to recover damages and civil penalties on behalf of the United States of America arising from the false claims presented, and or caused to be presented, by Defendants, in violation of the Federal False Claims Act, 31 U.S.C. §§ 3729 et seq., as amended.

2. The False Claims Act, (hereinafter the Act) originally enacted in 1863 during the Civil War, was substantially amended by the False Claims Amendments Act of 1986 and signed into law on October 17, 1986. Congress enacted these amendments to enhance the Government's ability to recover losses sustained as a result of fraud against the United States and to provide a private cause of action for the protection of employees who act in furtherance of the purposes of the Act. Congress amended the act after finding that fraud in federal programs and procurement is pervasive and that the False Claims Act, which Congress characterized as the primary tool for combating fraud in government contracting, was in need of modernization.

3. The Act provides that any person who knowingly submits a false or fraudulent claim to the Government for payment or approval is liable for a civil penalty of up to \$11,000 for each such claim, plus three times the amount of the damages sustained by the Government, including attorneys' fees. The Act allows any person having information regarding a false or fraudulent claim against the Government to bring a private cause of action for himself and on behalf of the Government and to share in any recovery. The complaint is to be filed under seal for 60 days (without service on the Defendant during such 60-day period) to enable the Government (a) to conduct its own investigation without the Defendant's knowledge and (b) to determine whether to join the

action.

4. Based on these provisions, Plaintiff/Relator seeks to recover damages and civil penalties arising from Defendants' presentation of fraudulent claims for payment and reimbursement by the United States Government for products that were manufactured in non-designated countries in violation of the Trade Agreements Act.

### **PARTIES**

5. Plaintiff/Relator Samuel Adam Cox III is a resident of Memphis, Tennessee and was formerly employed by Smith & Nephew, Inc. in its Tennessee office as the Information Technology Global Director of Enterprise Resource Planning. He was employed from mid-December 2007 to September 2008, when Smith & Nephew terminated him in retaliation for his objecting to his superiors about Smith & Nephew's illegal activities.

6. Defendant Smith & Nephew, Inc. ("Smith & Nephew") is a British medical devices company headquartered in London and active internationally. Smith & Nephew is constituent of the Financial Times Stock Exchange 100 Index, a share index of the 100 most capitalized companies on the London Stock Exchange. According to Smith & Nephew's website, Smith & Nephew operates in 32 countries and generates annual sales of \$3.4 billion. Over the last five years, the Company's revenue has increased from \$1.9 billion to over \$3.4 billion in 2007. The company employs over 9,600 people. Smith & Nephew has been violating the False Claims Act by selling products to the United States Government that were manufactured in non-designated countries.

### **JURISDICTION AND VENUE**

7. The Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331. It also has subject-matter jurisdiction pursuant to 31 U.S.C. §3732, which specifically provides for jurisdiction over actions brought under the False Claims Act, 31 U.S.C. §§3729 and 3730.

8. There has been no statutorily relevant public disclosure of the “allegations or transactions” in this Complaint.

9. This Court has personal jurisdiction over Defendant Smith & Nephew pursuant to 31 U.S.C. §3732(a) because that section authorizes nationwide service of process and because Defendant has at least minimum contacts with the United States. Moreover, Defendant is headquartered in and transacts – or has transacted – business in the Western District of Tennessee.

10. Venue is proper in this District pursuant to 31 U.S.C. §3732(a) because Defendant can be found in and transacts – or has transacted – business in the Western District of Tennessee.

### **BACKGROUND**

11. The Federal Trade Agreements Act (“TAA”) holds that in certain situations, U.S. Government Procurements from companies are subject to domestic preference requirements.

12. The TAA applies to acquisitions valued in excess of specified threshold amounts (revised about every two years). Currently, the TAA applies to products values in excess of about \$193,000, but the thresholds vary by type of acquisition, the government agency that is purchasing the product, and the product’s country of origin.

13. Under the TAA, if the value of the U.S. government's purchase is in excess of the applicable threshold, the U.S. Government can only then acquire either U.S.-made end products, or "Eligible Products" from a "Designated Country."

14. The categories of "designated countries" are: (1) WTO member and GPA signatory, (2) NAFTA country, (3) Caribbean Basin Country, (4) Least Developed Country, and, (5) for Department of Defense purchases, one of the 21 countries with which the U.S. has a "Memorandum of Understanding" ("MOU").

15. According to the TAA, if the value of the U.S. Government's purchase is in excess of the applicable threshold, the U.S. Government can only acquire the products if they meet the "End Product" test.

16. According to the End Product test, the end-product must either be: (a) mined, produced, or manufactured in the U.S. or a "Designated Country"; or (b) "Substantially Transformed" in the U.S. or a "Designated Country." "Substantial Transformation" means that the product is made into a "new and different article of commerce" with a name, character, or use distinct from that of article or articles from which it was transformed. An article is *not* substantially transformed by minor manufacturing or combining processes that leaves the identity of the article intact. The assembly process must be complex and meaningful.

17. Smith & Nephew is intentionally and knowingly selling non-complaint products to the United States government in violation of the Trade Agreements Act.

18. DELP Warehouse and the Global Distribution Center ("GDC") is part of Smith & Nephew's business operations in Memphis, Tennessee. The purpose of the GDC is to insure accurate fulfillment of customer orders in a timely manner. The GDC Project

was started in the first quarter of 2007, and it was managed by Tom Lenard.

19. Tom Leonard (Director of the GDC), Bill Griffin (Senior Vice President of Global Operations for Orthopaedics) and Jon Schaubert (Global Vice President of IT), held a meeting to discuss certain aspects of the GDC's business. The topics discussed were: the country of origin selection during sales order confirmations; product registration selections, as a product must be registered in a country in order to be sold in that country; and, "substantial transformation determination."

20. Bill Griffin and Jon Schaubert admitted in this meeting that they had personal knowledge that Smith & Nephew was shipping products from the DELP Warehouse to customers that violated Country of Origin laws and regulations. Nevertheless, they determined that no changes would be made to correct this problem. They scheduled the GDC project to continue unchanged for the second and third quarters of 2008.

21. Sal Chiovari, the Chief Information Officer for Smith & Nephew and a member of the Executive Staff overseeing the whole company, would not allow changes to the GDC project, even though he knew that the DELP Warehouse was making illegal shipments in violation of the Country of Origin laws and regulations. By not making changes to the GDC Project, these illegal shipments would continue.

22. In late January 2008, Plaintiff-Relator had a meeting with Tom Macelravery, VP of Sales/Supply Chain for Reconstructive surgery. Macelravery told Plaintiff-Relator that Smith & Nephew had a contract with the Department of Defense and was shipping products to the United States Military in violation of Country of Origin contract requirements and regulations. Macelravery claimed that this was true of the

entire customer base that Smith & Nephew was shipping to. That is, defendant was violating Country of Origin requirements not just with Department of Defense contracts, but with all hospitals and doctors. Macelravey joked to Plaintiff-Relator that this practice was “go to jail activity.”

23. That same week of late January, Plaintiff-Relator Cox met with David Ruff, the Director of Trauma Sales/Supply Chain. Ruff told Plaintiff-Relator that he knew Smith & Nephew was shipping “nails” that were made in Malaysia to the United States military, and that this was in direct violation of Country of Origin contractual requirements in the Department of Defense contracts. Plaintiff-Relator Cox told Ruff that this was a very serious violation and asked if Defendant has reported the error. Ruff said that Defendant had not. Plaintiff-Relator Cox told Ruff that this was “going to Jail activity.” Ruff smiled and stated that he would not look good in federal prison orange jump suits.

24. Smith & Nephew spent \$14 million for products in Malaysia in 2007. This is over 500,000 individual parts received at Smith & Nephew from Malaysia. This makes Malaysia Smith & Nephew’s largest supplier. Smith & Nephew’s products from Malaysia violate Country of Origin requirements and regulations.

25. In early February 2008, Plaintiff-Relator Cox met with Jon Schauber in his office to discuss Smith & Nephew’s Country of Origin violations. Cox recommended that the GDC project be corrected to remedy these violations, noting that continued violation of the Country of Origin laws and regulations could have severe penalties. Schauber responded that under no terms would there be a change in the GDC project, and threatened Plaintiff-Relator Cox that he better get on the “bus,” meaning that he better



“shut-up and go-along.”

26. In early February 2008, Plaintiff-Relator Cox also had a meeting with Steve Kahn, Vice President of Quality for Smith & Nephew. Kahn expressed his concern for the illegal activity surrounding shipments in fulfillment of the Department of Defense contracts. Kahn told Plaintiff-Relator that the nails that the United States military was receiving were being made in Malaysia, in direct violation of the Department of Defense contract requirements. Kahn stated that he was so concerned about this that he had raised the issue with Presidents of the Orthopedics Division, Mark Augusti and Joe Devivio. Kahn even started holding internal meetings with several Smith & Nephew departments to expose and try to gain internal awareness of the violation that were occurring on a daily basis. Kahn’s meetings were attended by some of Smith & Nephew Senior Management but never given any priority in the business objectives for the business.

27. In early February 2008, Jon Schaubert and Sal Chiovari directed Plaintiff-Relator Cox to undertake a “Country of Origin Batch Determination” project. In a meeting in early March, presided over by Bob Gaydos, it was joked that the Country of Origin project was a “keep Bob out of jail project.”

28. In early March 2008, Plaintiff-Relator Cox was in a meeting with Bob Gaydos, Senior Vice President of Global Orthopedic Operations. In attendance in this meeting were Win Ellard, Neil McGee, and Paul Cirbus. The topic that Smith & Nephew was in violation of several federal regulations was discussed in this meeting. Neil McGee suggested that a way around this problem was to have the boxes marked “Proudly Packaged in the USA.” Another idea considered was to have the product sent to Germany Operations and have it packaged there. Significant transformation would still

be in China, but the idea was to give the illusion of the product being produced in Germany by having it packaged there. It was also discussed at the meeting that nails that were manufactured in Malaysia were being shipped to the United States military, as well as other customers, in violation of the Federal Trade Agreement Act. Plaintiff-Relator Cox was shocked that Smith & Nephew executives would knowingly defraud the U.S. government and customers on devices that would be implanted in human beings, especially injured service men and women.

29. Smith & Nephew shipped nails to customers and to the United States military under false Country of Origin labeling.

30. When Plaintiff-Relator Cox refused to aid the violation of the Country of Origin laws and regulations, he was berated and cursed at by CIO, Sal Chiovari, who called Cox a variety of profanities. Further, Jon Schaubert threatened Cox, saying that he was going to give Cox a very poor grading on his performance review. Mr. Cox reported these fraudulent acts and punitive action to the whistleblower hotline, maintained by Smith & Nephew and administered by the Corporate Governance Committee of Smith & Nephew.

31. In September 2008, Smith & Nephew terminated Plaintiff-Relator Cox for refusing to participate in its illegal activities.

### **COUNT I**

*(False Claims Act, 31 U.S.C. §3729(a)(1) and (a)(2))*

32. Plaintiff/Relator realleges and incorporate by reference the allegations in the previous paragraphs of this Complaint.

33. This is a claim for treble damages and forfeitures under the False

Claims Act, 31 U.S.C. §§3729-32.

34. By virtue of the acts described above, Defendant Smith & Nephew knowingly submitted, caused to be submitted and continue to submit and to cause to be submitted false or fraudulent claims for payment and reimbursement by the United States Government for products that were manufactured in non-designated countries in violation of the Trade Agreements Act.

35. By virtue of the acts described above, the Defendants knowingly made, used or caused to be made or used, and continue to make or use or cause to be made or used, false statements to obtain Federal Government payment for false or fraudulent claims.

36. The United States Government has been severely damaged by the Defendants' violations as alleged above. The United States Government has been severely damaged because the Defendants have knowingly sold products to the United States Government from non-compliant countries. The United States has been severely damaged by the Defendant's violations of the False Claims Act.

37. As set forth in the preceding paragraphs, Defendants violated 31 U.S.C. §3729 and has thereby damaged and counties to damage the United States Government by its actions in an amount to be determined at trial.

## **COUNT II**

*(Violation of 31 U.S.C. §3730(h), Wrongful Discharge)*

38. The preceding paragraphs of this complaint are hereinafter realleged and incorporated by reference.

39. 31 U.S.C. §3730(h) states in pertinent part:

Any employee who is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment by his or her employer because of the lawful acts done by the employee on behalf of the employee or others in furtherance of an action under this section, including investigation for, initiation of, testimony for, or assistance in an action filed, or to be filed under this section, shall be entitled to all relief necessary to make the employee whole.

40. To make a prima facie case for retaliatory discharge under 3730(h) in most jurisdictions, the plaintiff/relator must show for the following: (1) that he took acts in furtherance of a qui tam suit, i.e. engaged in protected activity, (2) that his employer knew of the acts, and (3) that his employer discharged her as a result of these acts.

41. Mr. Cox engaged in protected activity by repeatedly advising his supervisors that he believed that Smith & Nephew had violated the law— specifically the Trade Agreements Act— when Smith & Nephew sold non-compliant products to the United States.

42. Mr. Cox communicated his concerns to several senior level officials. He also reported his concerns to the whistleblower hotline. Soon thereafter, he was terminated.

43. The timing of his discharge demonstrates that his discharge was motivated in part by illegal animus prohibited by 31 U.S.C. Section 3730(h).

44. As a result of this discharge, Mr. Cox has sustained loss of wages, emotional distress, and embarrassment.

### **PRAYER**

WHEREFORE, Plaintiff/Relator prays for judgment against Defendant as follows:

1. That Defendant ceases and desists from violating the Trade Agreements

Act.

2. That Defendant ceases and desists from violating 31 U.S.C. §3729 et seq;
3. That this Court enter judgment against the Defendant in an amount equal to three times the amount of damages the United States Government has sustained because of Defendant's actions, plus a civil penalty of not less than \$5,000 and not more than \$11,000 for each violation of 31 U.S.C. §3729 et seq;
4. That Plaintiff/Relator be awarded the maximum amount allowed pursuant to §3730(d) of the False Claims Act;
5. That Plaintiff/Relator Cox be awarded the maximum amount pursuant to §3730(h);
6. That Plaintiff/Relator be awarded all costs and expenses of this action, including attorneys' fees;
7. That Plaintiff/Relator recover such other relieve as the Court deems just and proper.

**DEMAND FOR JURY TRIAL**

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiffs-Relators hereby demand a trial by jury.

Respectfully Submitted,

By: s/Kevin H. Sharp  
Kevin H. Sharp, BPR # 016287  
**DRESCHER AND SHARP, P.C.**  
1720 West End Avenue, Suite 300  
Nashville, Tennessee 37212  
Telephone: (615) 425-7111  
Facsimile: (615) 425-7110

David W. Sanford  
**SANFORD, WITTELS & HEISLER, LLP**  
D.C. Bar No. 457933  
1666 Connecticut Avenue, NW, Suite 310  
Washington, D.C. 20009  
Telephone: (202) 742-7777  
Facsimile: (202) 742-7776

Grant Morris, D.C. Bar No. 926253  
**LAW OFFICES OF GRANT MORRIS**  
1666 Connecticut Ave., NW, Suite 310  
Washington, D.C. 20009  
Telephone: (202) 742-7783  
Facsimile: (202) 742-7776

**Counsel for Plaintiff/Relator**